

REMARKS

The present Amendment is in response to the Office Action dated August 12, 2004 in reference to the above-identified application. The Examiner set a shortened statutory period for reply of three (3) months, making the present Amendment due by November 12, 2004. Filed concurrently herewith is a request for a three-month extension of time so that the present Amendment is due by February 12, 2005, which is a Saturday, so that the present Amendment is due Monday, February 14, 2005.

In the Office Action, claims 28-64 are pending with claims 28-37 withdrawn from consideration by the Examiner pursuant to the restriction requirement under 35 U.S.C. § 121. In accordance with the restriction requirement, claims 38-64 were examined and each rejected under 35 U.S.C. §112 as being “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” The Examiner also rejected each of the claims under 35 U.S.C. 102(b) as being anticipated by either US Patent No. 4,943,433 to Rudov, WIPO publication WO 91/11191 or Australian Publication No. AU A 81985/87. In addition to this anticipation rejection, the Examiner rejects the pending claims under 35 U.S.C. §103(a) over any of these references alone.

Turning first to the Examiner’s Section 112 rejections, the Examiner takes the position that the terms used in the claims are “confusing”, noting in particular the term “primary substance”, which only appears in claims 38 and 39. Specifically, the Examiner states that use of this terminology “makes no sense” and further inquires as to whether Applicant is claiming water as a

primary substance. Applicant respectfully submits that the Examiner has failed to correlate the claim limitations to the disclosure and further, appears to have read Applicant's claims in a vacuum, which is impermissible pursuant to MPEP Section 2106.

More particularly, Section 2106(V)(A)(2) of the MPEP provides, in part,

Office personnel shall determine whether the claims set out and circumscribe the invention with a reasonable degree of precision and particularity. In this regard, the definiteness of the language must be analyzed, not in a vacuum, but always in light of the teachings of the disclosure as it would be interpreted by one of ordinary skill in the art. Applicant's claims, interpreted in light of the disclosure, must reasonably apprise a person of ordinary skill in the art of the invention. However, the applicant need not explicitly recite in the claims every feature of the invention. For example, if an applicant indicates that the invention is a particular computer, the claims do not have to recite every element or feature of the computer. In fact, it is preferable for claims to be drafted in a form that emphasizes what the applicant has invented (i.e., what is new rather than old). *In re Dossel*, 115 F.3d 942, 946, 42 USPQ2d 1881, 1884 (Fed. Cir. 1997). (emphasis added).

Applicant notes for the Examiner's attention that the term "primary substance" is used in the disclosure. For example, with reference to the pagination of WO 01/22980, the Examiner will note that on page 2, beginning on line 23, the disclosure provides "... The method including a primary chemical treatment involving the administration of a primary substance, the primary treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating animals" (page 2, line 23 – page 3, lined 2) (emphasis added). Accordingly, Applicant submits that a person of ordinary skill in this art would readily understand the term "primary substance" when interpreted in light of Applicant's disclosure. Furthermore, Applicant submits

that an appropriate 112 analysis of claim 38 would not result in the interpretation that the “primary substance” of Applicant’s invention is “water”.

Moreover, claim 39 recites “said primary substance is an antibiotic”. It is not clear from the Examiner’s Office Action why, at the very minimum, the term “primary substance”, as used in claim 39 is considered to be indefinite. Moreover, Applicant submits that the terminology of each of the pending claims make sense when both correlated with Applicant’s disclosure and viewed from the perspective of one ordinary skilled in the art.

Additionally, the Examiner asserts “the claims also are confusing since they do not definitely define what is in the composition” and “the claims are claiming a product and should be claimed as such”. MPEP Section 2173.02 provides, in part:

The examiner’s focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. Some latitude of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.

Indeed, Applicant is claiming a product, and submits that the claim language chosen in each of the claims provides for the components of this product and that such components are clearly defined. While Applicant may not be using claim terminology that the Examiner may have chosen, it is Applicant’s prerogative so long as the terminology is clear and precise. Again, when

these terms are correlated with Applicant's disclosure and viewed from the perspective of one ordinarily skilled in the art, the terms are clear, precise, and make sense.

Aside from Applicant's use of the term "primary substance", Applicant notes the lack of specificity and sufficiency of the Examiner's arguments in rejecting all of the claims under Section 112. In light of this, Applicant is only able to respond to the Section 112 rejection as it pertains to claims 38 and 39 and reserves the right to supplement its response at such time the Examiner fully articulates the Section 112 rejection of the remainder of its pending claims. Accordingly, Applicant respectfully requests that the Examiner's 112 rejections be removed from all of the pending claims based upon the foregoing arguments.

Notwithstanding the foregoing, Applicant has chosen to amend independent claims 38, 52, and 60 in an effort to further clarify the scope of the claimed invention. Particularly, Applicant notes that claim 38 recites a composition having three components – (1) a primary substance operative to treat the animal's condition; (2) a secondary substance operative to reduce the incidence or severity of side effects caused by the primary substance; and (3) a carrier or excipient suitable for application to and take up of both the primary substance the secondary substance by the animal. Applicant submits that claim 38 defines Applicant's invention with sufficient clarity and precision so as to address the Examiner's 112 rejection and respectfully requests that the rejection be removed from claim 38 and its dependent claims 39-51.

In addition, Applicant notes for the Examiner's attention that clarifying amendments have also been made to independent claims 52 and 60. Particularly, independent claim 52 now recites a pharmaceutical composition that includes as a component thereof an antibiotic operative to infections and a liquid extract operative to treat side effects associated with the antibiotic. Finally, Claim 60 has been amended to provide a pharmaceutical composition that comprises an antibiotic that is "operative to treat chronic fatigue syndrome" as well as a liquid extract operative to alleviate side effects associated therewith.

In amending claims 38, 52, and 60 in this way, Applicant submits that it has also addressed the Examiner's Section 102(b) and 103(a) rejections. In each of these claims, the primary substance, antibiotic, and liquid extract are now recited so as to be "operative to" treat specified conditions or infections, as recited in the specific claims. Specifically, claim 38 recites that the primary substance is operative to treat a condition selected from a pathological condition, an injured condition, an abnormal condition, and an immuno compromised condition. In claim 52, the antibiotic is operative to treat infections resulting from surgery, while claim 60 recites an antibiotic that is operative to treat chronic fatigue syndrome. In addition, in each of these amended claims, the claim has been recited so that the liquid extract component is operative to treat at least one side effect associated with the primary substance or antibiotic.

None of the cited references teach or even suggest a primary substance or antibiotic that is operative to effectively treat the aforesaid

conditions or infections. It also follows that none of the cited references teach or suggest a liquid extract operative to treat the side effects associated with the primary substance or antibiotic. As set forth in a previous response, the cited references describe the use of cereal plant extracts for the treatment of various maladies such as cold sores, skin lesions, tumours and viral infections, to improve a patient's immunity and as an analgesic. None of the references teach an antibiotic or primary substance operative to treat the conditions so recited in the claims. The only "antibiotic" component taught in the cited references is that of the microbial agent. In the references, however, the microbial agent is analogous to a disinfectant that is merely useful to prevent spoilage of the overall composition. In the present invention, however, the "antibiotic" component is analogous to substance, such as penicillin or streptomycin, which is operative to treat the condition or infection presenting in the animal. None of the references cited teach or even suggest a primary substance or antibiotic of this nature or the treatment of the side effect associated therewith, as now recited in the amended claims. Accordingly, Applicant respectfully submits that pending claims 38-60 are now in condition for allowance

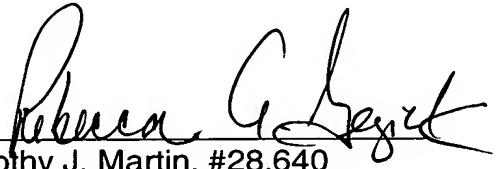
No additional claims fees are believed to be payable upon the Amendment. However, the Commissioner is hereby authorized to charge any deficiency in the required fees, or to credit any overpayment, to deposit account number 13-1940.

Based on the foregoing, Applicant submits that the present application is in complete condition for allowance, and action to that end is courteously

solicited. If any issues remain to be resolved prior to the granting of this application, the Examiner is requested to contact the undersigned attorney for the Applicant at the telephone number listed below.

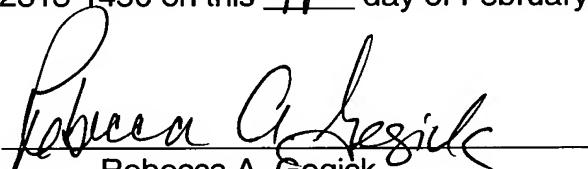
Respectfully submitted,

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CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8

I hereby certify that the foregoing **AMENDMENT (14 pages)**, and **Request for a three-month Extension of Time (2 pages)** is being deposited with the United States Postal Service as first-class mail in an envelope addressed to Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 14th day of February, 2005.


Rebecca A. Gegick